

suspension which, upon being shaken a reasonable length of time, would insure a uniform distribution of solid in vehicle and, therefore, uniform and proper dosage.

DISPOSITION: 9-20-60. Default—destruction.

**6489. Sodium para-aminosalicylic acid tablets.** (F.D.C. No. 43394. S. No. 61-104 P.)

QUANTITY: 74 24-btl. cartons and 25 btls. at Detroit, Mich.

SHIPPED: Between 5-22-59 and 6-4-59, from Auburn, Mass., by Cowley Pharmaceuticals, Inc.

LABEL IN PART: "1,000 Tablets Salamin Sodium Each Tablet Contains: Sodium Para-Aminosalicylic Acid 0.5 grams (7.72 grains)."

RESULTS OF INVESTIGATION: Examination showed that the article contained 87.6 percent of the labeled amount of sodium para-aminosalicylic acid; that the average weight of tablets in two subdivisions was below declared weight of active ingredient; and that a substantial number of broken tablets were found in the sample. United States Pharmacopeia requires *sodium para-aminosalicylic acid tablets* to contain from 95 to 105 percent of labeled amount of the drug.

LIBELED: 7-22-59, E. Dist. Mich.

CHARGE: 501(b)—when shipped, the article purported to be a drug recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below the standard set forth in the compendium; 502(a)—the label statement "Each tablet contains: Sodium Para-Aminosalicylic Acid 0.5 grams (7.72 grains)" was false and misleading.

DISPOSITION: 12-28-60. Consent—claimed by shipper and reconditioned to be brought into compliance with the law.

**6490. Posterior pituitary injection.** (F.D.C. No. 45135. S. No. 41-134 R.)

QUANTITY: 12 vials at St. Louis, Mo.

SHIPPED: 8-22-60, from Chicago, Ill., by Medical Chemicals Corp.

LABEL IN PART: (Vial) "10 cc Sterile Multiple Dose Vial Posterior Pituitary Injection 10 U. S. P. Units/cc (Obstetrical) 0.5 Chlorobutanol \* \* \* Medical Chem. Corp. Chicago 51, Ill. 6132."

RESULTS OF INVESTIGATION: Analysis showed that the potency of the article was not more than 4.6. U. S. P. posterior pituitary units per cubic centimeter.

LIBELED: 11-7-60, E. Dist. Mo.

CHARGE: 501(b)—when shipped, the strength of the article fell below the standard set forth in the United States Pharmacopeia; and 502(a)—the label statement "Posterior Pituitary Injection 10 U. S. P. Units/cc" was false and misleading.

DISPOSITION: 12-14-60. Default—destruction.

**6491. Rubber prophylactics.** (F.D.C. No. 44536. S. No. 32-793/5 R.)

QUANTITY: 56 ctns., each containing 48 3-unit paper sleeves; 138 ctns., each containing 48 3-unit plastic cans; 198 ctns., each containing 12 paper sleeves of 4 3-unit paper packs, at Brooklyn, N.Y.

SHIPPED: 2-16-60 and 3-18-60, from Akron, Ohio, by March Rubber & Plastic Co.

**LABEL IN PART:** (Ctn. and sleeve of 56-ctn. lot) "Gladiator 3 pack reservoir end \* \* \* Prophylactics"; (can of 138-ctn. lot) "Sold for the prevention of disease only Gladiator transparent thins"; and (ctn. and sleeve of 198-ctn. lot) "Checks Deluxe Thin Prophylactics."

**RESULTS OF INVESTIGATION:** Examination revealed that 3 out of 96 units of the article in the 56-ctn. lot, 3 out of 144 units of the article in the 138-ctn. lot, and 3 out of 150 units of the article in the 198-ctn. lot contained holes.

**LIBELED:** 4-29-60, E. Dist. N.Y.

**CHARGE:** 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess; 502(a)—the label statements "Prophylactics" (56-ctn. and 198-ctn. lots) and "Sold for the prevention of disease only" (138-ctn. lot) were false and misleading as applied to a product which contained holes.

**DISPOSITION:** 6-23-60. Consent—claimed by the shipper and destroyed.

### **DRUGS AND DEVICE ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS\***

**6492. Safflower seed oil, soy oil, vitamin B<sub>2</sub> tablets, vitamin A capsules, V-Complete multivitamin and mineral tablets, Super Potency multivitamin and mineral tablets, Liverall tablets, vitamin C, vitamin B complex tablets, brewer's yeast powder and tablets, wheat germ cereal, flaked yeast, sunflower seeds.** (F.D.C. No. 45016. S. Nos. 8-481/3 R, 8-485/95 R.)

**QUANTITY:** 1 150-lb. drum, and 3 qt. btls., 21 pt. btls., and 3 gal. containers, of safflower seed oil; 50 qt. btls., 57 pt. btls., and 6 gal. btls., of soy oil; 17 100-tablet btls. of vitamin B<sub>2</sub>; 1 100-capsule btl., and 5 250-capsule btls. of vitamin A; 4 300-tablet btls., 6 100-tablet btls., and 7 60-tablet btls., of V-Complete multivitamins and minerals; 11 300-tablet btls., 2 100-tablet btls., and 6 60-tablet btls., of Liverall; 4 4-lb. jars, and 11 1-lb. jars, of brewer's yeast; 11 1,000-tablet btls. of brewer's yeast; 47 100-tablet btls. of Super Potency multivitamin and minerals; 22 100/100 mg. btls., 15 250/100 mg. btls., 5 500/100 mg. btls., 1 250/200 mg. btl., and 5 500/250 mg. btls., of vitamin C; 3 100-tablet btls., 17 250-tablet btls., and 6 500-tablet btls., of vitamin B complex; 5 ctns., 12 9-oz. pkgs. each, of wheat germ cereal; 148 1-lb. bags of flaked yeast; and 120 12-oz. jars, 134 1-lb. packs, and 4 50-lb. bags, of sunflower seeds, at Rochester, N.Y., in possession of Niblack Foods, operating a retail outlet under the name of Dietary Specialties.

**SHIPPED:** Between the approximate dates of 12-31-58 and 8-3-60, from various places outside the State of New York.

**LABEL IN PART:** (Btls.) "Niblack's Safflower Seed Oil 92% Unsaturated Fatty Acids Contents \* \* \* Packed by Niblack Foods, Rochester 8, N.Y.," "Niblack's Soy Oil Contents \* \* \* Niblack Foods, Rochester 8, N.Y.," "Thompson's Standardized Vitamins Vitamin B<sub>2</sub> 10 Milligrams HH 2579 Each tablet contains 10 Milligrams of Riboflavin (Vitamin B<sub>2</sub>)," "Thompson's Standardized Vitamins Vitamin A 20,000 U.S.P. Units Per Tablet #13328," "V-Complete Natural Vitamins Natural Minerals Organic Iron+B<sub>12</sub> \* \* \* A Food Supplement Providing an Excellent Source of Food Derived Vitamins and Minerals Skillfully Combined with an Organic Iron Compound," and "Schiff Natural Liverall Desiccated Low Heat Dried Liver"; (jar) "Schiff

\*See also Nos. 6485-6487, 6489-6491.